

JUN 15 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Carcagno *et al.*

Appl. No. 09/830,964

Filed: May 3, 2001

For: **Methods of Purifying Recombinant
Human Erythropoietin from Cell
Culture Supernatants**Art Unit: *To Be Assigned*Examiner: *To Be Assigned*

Atty. Docket: 1909.0030002/JAG/CMB

Information Disclosure StatementCommissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AT3, AR4, AS4 and AT4 cited on Form PTO 1449:

Documents AT3, AR4, AS4 and AT4 are in the French language. No English translations are readily available. These documents appear to show evidence of a substance isolated from blood capable of regulating hematopoiesis.

Document AT11 is in a foreign language. An English language abstract is on the first page of this document.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 09/830,967, filed May 3, 2001, submitted herewith as Document AS17; and

U.S. Patent Application No. 09/830,968, filed May 3, 2001, submitted herewith as Document AT17.

BEST AVAILABLE COPY

FORM PTO-1649		ATTY. DOCKET NO. 1909.0030002/JAG/G-3		APPLICATION NO. 09/830,966			
INFORMATION DISCLOSURE STATEMENT		APPLICANT Coreogno et al.					
		FILING DATE May 3, 2001		GROUP To Be Assigned			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,667,016	05/19/1987	Lai et al.	530	397	06/20/1985
	AB1	4,667,195	06/30/1987	Neufek et al.	530	397	01/11/1985
	AC1	4,703,008	10/27/1987	Lin	435	240.2	11/30/1986
	AD1	4,806,524	02/21/1989	Kanaguchi et al.	514	8	10/03/1985
	AE1	5,010,002	04/23/1991	Levinson et al.	435	69.2	03/22/1990
	AF1	5,547,933	08/20/1996	Lin	514	8	06/07/1995
	AG1	5,618,698	04/08/1997	Lin	435	69.4	06/06/1995
	AH1	5,688,679	11/18/1997	Powell	435	240.2	10/06/1993
	AI1	5,736,349	05/26/1998	Lin	435	325	05/06/1995
	AJ1	5,783,559	07/21/1998	Florin-Robertson et al.	514	12	01/10/1994
	AK1						
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WD 86/03520	06/19/1986	WIPO/PCT			Yes No
	AM1	WD 98/00530	01/08/1998	WIPO/PCT			Yes No
	AN1	WD 00/27419	05/18/2000	WIPO/PCT			Yes No
	AO1	WD 00/27869	05/18/2000	WIPO/PCT			Yes No
	AP1	WD 00/27997	05/18/2000	WIPO/PCT			Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	1	Andersen, D.C. and Gooch, C.F., "The effect of cell-culture conditions on the oligosaccharide structures of secreted glycoprotein," <i>Curr. Op. Biotech.</i> 5:544-549, Current Biology Ltd. (1994).				
	AS	1	Bondurant, M.C. and Koury, M.J., "Anemia Induces Accumulation of Erythropoietin mRNA in the Kidney and Liver," <i>Mol. Cell. Biol.</i> 6:2731-3, American Society for Microbiology (1986).				
	AT	1	Borsook, H., et al., "Polycythemic Response in Normal Adult Rats to a Nonprotein Plasma Extract from Anemic Rabbits," <i>Blood</i> 9:734-742, Grune and Stratton, Inc. (1954).				
EXAMINER				DATE CONSIDERED			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
1909.0030002/JAG/C33APPLICATION NO.
09/830,964APPLICANT
Carceano et al.FILING DATE
May 3, 2001GROUP
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 00/28066	03/18/2000	HIPD/PCY			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Borio, J.U., et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> 247:1306-1310, American Association for the Advancement of Science (1990).
	AS	2	Brown, P.R. and Krstulovic, A.H., "Practical Aspects of Reverse-Phase Liquid Chromatography Applied to Biochemical and Biomedical Research," <i>Anal. Biochem.</i> 99:1-21, Academic Press, Inc. (1979).
	AT	2	Burg, J., et al., "Human erythropoietin recombinant production by fermentation and protein purification using a series of chromatographic steps," <i>Chem. Abstracts</i> 126:315 Abstract No. 57095], American Chemical Society (1997).

EXAMINER

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FORM PTO-1649 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1909.0030002/JAG/CB		APPLICATION NO. 09/830,966	
APPLICANT Carcagno et al.		FILING DATE May 3, 2001		GROUP To Be Assigned	

U.S. PATENT DOCUMENTS							
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	3	Busuttil, R.H., et al., "The Cytological Localization of Erythropoietin in the Human Kidney Using the Fluorescent Antibody Technique," <i>Proc. Soc. Exp. Biol. Med.</i> 137:327-330, Academic Press, Inc. (1971).
	AS	3	Busuttil, R.H., et al., "Localization of Erythropoietin in the Glomerulus of the Hypoxic Dog Kidney Using a Fluorescent Antibody Technique," <i>Acta Haemat.</i> 47:238-242, S. Karger (1972).
	AT	3	Carnot, M.P. and Deflandre, C., "Sur l'activité hémoépérétique du sérum au cours de la régénération du sang," <i>C.R. Acad. Sci.</i> 143:384-386, (1906).

EXAMINER	DATE CONSIDERED
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FORM PTO-1649 INFORMATION DISCLOSURE STATEMENT		ATTY. DORSEY CO. 1909.0030002/JAG/CMB		APPLICATION NO. 09/830,964			
		APPLICANT Carcagno et al.					
		FILING DATE Nov 3, 2001		GROUP To Be Assigned			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	4	Carnot, H.P. and Deflandre, C., "Sur l'activité hématopoïétique des différents organes au cours de la régénération du sang," C.R. Acad. Sci. 143:432-435 (1906).				
	AS	4	Carnot, H.P., "Sur le Mécanisme de L'hypoglobulie Provoquée par le Sérum D'animal en Régénération Sanguine," C.R.H. Sean. Mem. Soc. Biol. 111:344-346, Librairie de L'Académie de Médecine (1906).				
	AT	4	Carnot, H.P., "Sur L'activité Cytopoïétique du Sang et des Organes Régénérés au Cours des Régénérations Viscérales," C.R.H. Sean. Mem. Soc. Biol. 111:463-465, Librairie de L'Académie de Médecine (1906).				
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FORM PTO-1649		ATTY. DOCKET NO. 1909.0030002/JAG/CK3		APPLICATION NO. 09/830,966	
INFORMATION DISCLOSURE STATEMENT		APPLICANT Carcano et al.			
		FILING DATE May 3, 2001		GROUP To Be Assigned	

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	2	Caro, J. and Erslev, A.J., "Biologic and immunologic erythropoietin in extracts from hypoxic whole rat kidneys and in their glomerular and tubular fractions," J. Lab. Clin. Med 103:922-931, C.V. Mosby Company (1984).	
AS	2	Caro, J., et al., "Erythropoietin Production by an Established Kidney Proximal Tubule Cell Line (LLCPK)," Exp. Hematol 12:357, Springer-Verlag (1984).	
AT	2	Caro, J., et al., "Erythropoietin in liver tissue extracts and in liver perfusates from hypoxic rats," Am. J. Physiol. 244:E431-E434, American Physiological Society (1983).	

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		APPLICANT Carcano et al.			
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	6	Dinkelaar, R.D., et al., "Metabolic Studies on Erythropoietin (Ep): II. The Role of Liver and Kidney in the Metabolism of Ep," <i>Exp. Hematol.</i> 9:796-803, Allen Press, Inc. (1981).
	AS	6	Dornfest, B.S., et al., "Hepatic production of erythropoietin in a phenylhydrazine-induced compensated hemolytic state in the rat," <i>J. Lab. Clin. Med.</i> 102:274-85, C.V. Mosby Company (1983).
	AT	6	Dornfest, B.S., et al., "Recovery of an Erythropoietic Inducing Factor from the Regenerating Rat Liver," <i>Ann. Clin. Lab. Sci.</i> 11:37-46, Institute for Clinical Science (1981).

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APPLICANT Corcagno et al.		FILING DATE May 3, 2001		GROUP To Be Assigned	

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Portinant Pages, etc.)			
	AR	Z	Erslev, A., "Humoral Regulation of Red Cell Production," <i>Blood</i> 8:349-357, Grune and Stratton, Inc. (1953).
	AS	Z	Erslev, A.J., "In Vitro Production of Erythropoietin by Kidneys Perfused With a Serum-free Solution," <i>Blood</i> 44:77-85, Grune and Stratton, Inc. (1974).
	AT	Z	Erslev, A.J. and Caro, J., "Physiologic and Molecular Biology of Erythropoietin," <i>Med. Oncol. Tumor Pharmacother.</i> 3:159-166, Pergamon Press (1986).

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		APPLICANT Cereagno et al.		FILING DATE May 3, 2001		
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)						
	AR	B	Eschbach, J.W., et al., "Correction of the Anemia of End-Stage Renal Disease with Recombinant Human Erythropoietin," <i>New Eng. J. Med.</i> 316:73-78, Massachusetts Medical Society (1987).			
	AS	B	Fisher, J.W. and Birdsell, B.J., "The Production of an Erythropoietic Factor by the In Situ Perfused Kidney," <i>Acta. Haemat.</i> 26:224-232, S. Karger (1961).			
	AT	B	Fisher, J.W., et al., "Localization of Erythropoietin in Glomeruli of Sheep Kidney by Fluorescent Antibody Technique," <i>Nature</i> 205:611-612, Macmillan Magazines Ltd. (1965).			
EXAMINER					DATE CONSIDERED	
EXAMINER: Initial 19 reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.						

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1909.0030002/JAG/CMB		APPLICATION NO. 09/830,964	
FILING DATE May 3, 2001		APPLICANT Carcano et al.			
GROUP To Be Assigned					

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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AR	2	Fisher, J.U., "Pharmacologic Modulation of Erythropoietin Production," <i>Ann. Rev. Pharmacol. Toxicol.</i> 28:101-122, Annual Reviews, Inc. (1988).
	AS	2	Frenkel, E.P., et al., "Some Observations on the Localization of Erythropoietin," <i>Ann. N.Y. Acad. Sci.</i> 149:292-293, New York Academy of Sciences (1968).
	AT	2	Gordon, A.S., et al., "A Plasma Extract with Erythropoietic Activity," <i>Proc. Soc. Exp. Biol. Med.</i> 86:255-258, Society for Experimental Biology and Medicine (1954).

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 INFORMATIONAL DISCLOSURE STATEMENT				ATTY. DOCKET NO. 1909.0030002/JAG/CMB		APPLICATION NO. 09/830,964	
FILING DATE May 3, 2001				GROUP To Be Assigned			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	10	Han, F., et al., "Cloning of a human erythropoietin cDNA and its expression in COS-7 cells," <i>Chem. Abstracts Abstract No. 511352 (1996)</i> .				
	AS	10	Hodgson, G. and Toth, J., "The Erythropoietic Effect of Urine and Plasma of Repeatedly Bled Rabbits," <i>Blood</i> 9:299-309, Grune and Stratton, Inc. (1954).				
	AT	10	Jacobs, K., et al., "Isolation and characterization of genomic and cDNA clones of human erythropoietin," <i>Nature</i> 313:806-810, Macmillan Magazines Ltd. (1985).				
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FORM PTO-1649 INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 1909.0030002/JAG/CXB		APPLICATION NO. 09/830,986	
				APPLICANT Carcagno et al.			
				FILING DATE May 3, 2001		GROUP To Be Assigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	11	Jacobson, L.O., et al., "Role of the Kidney in Erythropoiesis," <i>Nature</i> 179:633-634, Macmillan Magazines Ltd. (1957).				
	AS	11	Jellmann, H., et al., "Extraction of Erythropoietin from Isolated Renal Glomeruli of Hypoxic Rats," <i>Exp. Hematol.</i> 11:581-588, Allen Press, Inc. (1983).				
	AT	11	Jixian, D., et al., "Study on a serum-free medium used for production of rHuEPO," <i>Bull. Acad. Mil. Med. Sci.</i> 21:244-246, Academy of Military Medical Sciences (1997).				
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	12	Kozel, L.A. and Erolov, A.J., "Erythropoietin Production in Renal Tumors," <i>Ann. Clin. Lab. Sci.</i> 5:98-109, Institute for Clinical Science (1975).
AS	12	Krona, N.K., "The Role of Erythropoietin in the Anemia of Chronic Renal Failure," <i>H. Ford Hosp. Med. J.</i> 31:177-181, Henry Ford Hospital (1983).
AT	12	Koury, S.T., et al., "Localization of Erythropoietin Synthesizing Cells in Murine Kidneys by In Situ Hybridization," <i>Blood</i> 71:524-527, Grune and Stratton, Inc. (1988).

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U.S. PATENT DOCUMENTS

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	13	Koury, S.T., et al., "Quantitation of Erythropoietin-Producing Cells in Kidneys of Mice by In Situ Hybridization: Correlation With Hematocrit, Renal Erythropoietin mRNA, and Serum Erythropoietin Concentration," <i>Blood</i> 74:645-651, Grune and Stratton, Inc. (1989).
AS	13	Kureczko, Z., et al., "Studies on the Production of Erythropoietin by Isolated Perfused Organs," <i>Blood</i> 18:527-534, Grune and Stratton, Inc. (1961).
AT	13	Kurtz, A., et al., "Renal mesangial cell cultures as a model for study of erythropoietin production," <i>Proc. Natl. Acad. Sci. USA</i> 80:4008-4011, National Academy of Sciences (1983).

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INFORMATION DISCLOSURE STATEMENT		APPLICANT Carpoceno et al.		FILING DATE May 3, 2001	
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	AL				Yes
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	AM				Yes
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	AN				Yes
					No
	AO				Yes
					No
	AP				Yes
					No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)					
	AR	14	Locorbo, C., et al., "Peritubular Cells Are the Site of Erythropoietin Synthesis in the Murine Hypoxic Kidney," J. Clin. Invest. 81:620-623, Rockefeller University Press (1988).		
	AS	14	Liu, P., et al., "Hepatic Erythropoietin (Ep) Production Following Double Partial Hepatectomy in the Rat," J. Surg. Oncol. 15:121-132, Alan R. Liss, Inc. (1980).		
	AT	14	Naughton, B.A., et al., "Reticuloendothelial System (RES) Hyperfunction and Erythropoietin (Ep) Production in the Regenerating Liver," J. Surg. Oncol. 12:227-242, Alan R. Liss, Inc. (1979).		
EXAMINER				DATE CONSIDERED	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.					

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DCKET NO.
1909.0030002/JAG/CMBAPPLICATION NO.
09/830,964APPLICANT
Coreoena et al.FILING DATE
May 3, 2001GROUP
To Be Assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	15	Naughton, B.A., et al., "Evidence for a Hepatic-Renal Antagonism in the Production of Hepatic Erythropoietin," <i>Ann. Clin. Lab. Sci.</i> 13:432-438, Institute for Clinical Science (1983).
AS	15	Persons, T.P., et al., "Rapid and Easy Separation of the Subunits of Bovine and Human Glycoprotein Hormones by Use of High Performance Liquid Chromatography," <i>Endocrinology</i> 114: 2223-2227, J.B. Lippincott Co. (1985).
AT	15	Reisman, K.R., "Studies on the Mechanism of Erythropoietic Stimulation in Parabolic Rats During Hypoxia," <i>Blood</i> 5:372-380, Grune and Stratton, Inc. (1950).

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May 3, 2001GROUP
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL						Yes No
AM						Yes No
AN						Yes No
AO						Yes No
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AR	16	Schuster, J.H., et al., "Physiologic Regulation and Tissue Localization of Renal Erythropoietin Messenger RNA," <i>Blood</i> 70:316-318, Grune and Stratton, Inc.(1987).
AS	16	Sherwood, J.B., et al., "Erythropoietin Production by Human Renal Carcinoma Cells in Culture," <i>Endocrinology</i> 99:504-510, J.B. Lippincott Co. (1976).
AT	16	Takagaki, Y., et al., "Amino Acid Sequence of the Membranous Segment of Rabbit Liver Cytochrome b," <i>J. Biol. Chem.</i> 255:1536-1541, American Society of Biological Chemists, Inc. (1980).

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				APPLICANT Corcoran et al.			
				FILING DATE May 3, 2001		GROUP To Be Assigned	
U.S. PATENT DOCUMENTS							
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
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							No
	AM						Yes
							No
	AN						Yes
							No
	AO						Yes
							No
	AP						Yes
							No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	18	International Search Report of International Application No. PCT/US99/26238, March 7, 2000.				
	AS	18	International Search Report of International Application No. PCT/US99/26241, March 7, 2000.				
	AT	18	International Search Report of International Application No. PCT/US99/26240, February 22, 2000.				
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	12	International Search Report of International Application No. PCT/US99/26237, February 18, 2000.				
	AS	12					
	AT						

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